

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
LEUNG *et al.*

Serial No.: 09/988,013

Filed: November 16, 2001

Title: IMMUNOCONJUGATES AND HUMANIZED
ANTIBODIES SPECIFIC FOR B-CELL
LYMPHOMA AND LEUKEMIA CELLS

Group Art Unit: 1643

Examiner: David Blanchard

Attorney Docket No.: IMMU-0014US2

Confirmation No.: 7681

VIA EFS-WEB

DECLARATION

COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

Sir:

I, Barbara A. McDowell, declare as follows:

I represent Immunomedics in the above-identified application before the USPTO. Since receiving the decision on petition dated December 13, 2010, in this case I have made the following attempts to obtain Dr. Leung's signature on a declaration under 37 CFR 1.131.

On March 15, 2011, I sent, via Federal Express International Priority Service, a final revised version of the declaration which included all of Dr. Leung's input as conveyed to me by Dr. Leung's attorney, Gregory Lantier. I used the most recent address known to applicant for Dr. Leung. The address was one that was given by Dr. Leung in an affirmation filed on October 30, 2007, in Action No. 1767 of 2007, in the High Court of the Hong Kong Special Administrative Region. This affirmation was filed in connection with ongoing litigation with Immunomedics.

The declaration which was sent to Dr. Leung was accompanied by a cover letter which stated that "If you do not return the declaration within one month, *i.e.*, by April 14, 2011, we shall take that as a refusal on your part to execute the declaration in accordance with the terms of

your employment agreement with Immunomedics, Inc.” Also included was a prepaid envelope for return of the executed declaration.

On March 18, 2011, my office was informed by Federal Express that Dr. Leung had moved, and we were asked whether an undated address could be provided. I then contacted Gregory Lantier, however he was unable to share a more current address for Dr. Leung. Subsequently, the Federal Express package was returned to my office, with a notation that Dr. Leung had moved, dated March 18, 2011. A copy of the declaration and the cover letter, as well as the Federal Express label, and a copy of the stamped returned package are attached in Appendix A.

Upon learning that Dr. Leung had moved, I next sent, on March 23, 2011, a second package, using the USPS International Guaranteed service, using a newly dated cover letter, and again providing a prepaid envelope for return of the enclosed declaration. The reason for this second attempt was to have a package that would route through the Hong Kong postal service, which might know of a forwarding address for Dr. Leung. I personally contacted the help line of the USPS International branch, and also had a staff member hand carry the package to the Post Office to ascertain what would happen vis-à-vis forwarding in Hong Kong, *i.e.*, whether the package would be forwarded by the Hong Kong postal service and what would be communicated back to us. The reply in both instances was that the forwarding of mail by a foreign postal service was not within their control, and there was no way of ascertaining whether the package would be forwarded. This second package also was returned to my office, with the notation “addressee unknown.” A copy of the cover letter, as well as the USPS Express Mail label, and a copy of the stamped returned package are attached in Appendix B.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

May 4, 2011

Date

/Barbara A. McDowell/

Barbara A. McDowell
Reg. no. 31,640

APPENDIX A

Rossi, Kimms & McDowell LLP

Intellectual Property Law

20609 Gordon Park Square
Suite 150
Ashburn, VA 20147

Phone: 703-726-6020
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Mail@RKMLegalGroup.com

14 March 2011

Dr. Shui-On Leung
10B, St. George Apartments,
81 Waterloo Road,
Kowloon,
Hong Kong

Re: US Patent Application Serial No. 09/988,013 (Immunomedics, Inc.)

Dear Dr. Leung,

Further to input from you in October and November 2009 regarding a declaration under 37 CFR 1.132 for your review and signature, we now provide you with a revised declaration addressing your comments. Please review and sign the enclosed declaration and return it to me in the enclosed self-addressed and pre-paid envelope. If you do not return the declaration within one month, *i.e.*, by April 14, 2011, we shall take that as a refusal on your part to execute the declaration in accordance with the terms of your employment agreement with Immunomedics, Inc.

Sincerely,

ROSSI, KIMMS & McDOWELL LLP

/Barbara A. McDowell/

Barbara A. McDowell

Enclosures:
Declaration under 37 CFR 1.132 for execution
by Dr. Leung
Addressed and pre-paid envelope for return of
declaration

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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VIA EFS-WEB

DECLARATION UNDER 37 CFR § 1.131

COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

Sir:

I, Shawn Leung, being duly warned, declare as follows:

I am a co-inventor of the above-identified application.

Attached is a copy of a monthly progress report submitted by me while I was employed by Immunomedics, Inc. as Associate Director in Molecular Biology, reporting work done at Immunomedics. The date on the monthly progress report has been redacted, but was before April 28, 1994.

The report discusses chimeric LL2, humanized LL2.1 (HuLL2) and humanized LL2.2 (mutHuLL2).

Also attached is a copy of a page from my Immunomedics lab notebook entitled "DNA Sequence of LL2 Gamma Chain Variable Region as Cloned Out Using CHIA and VH1Back Primers in a PCR Reaction," recording work done at Immunomedics. The date on the computer print-out page has been redacted, but was before April 28, 1994.

The page from the laboratory notebook shows sequence comparison of the LL2 heavy chain to three of the most commonly used human heavy chain frameworks for CDR grafting at the time. They were, namely, EU, NEW and KOL. A summary on the number of amino acid mismatches to the corresponding FR1, FR2 and FR3 of murine LL2 heavy chain was listed. It indicates at the bottom EU framework matches better with LL2. Looking at the left of the start of the murine LL2 sequence, there are hand written residues. Those which differ for NEWM are hand written above, and those that differ for KOL are written below, the murine LL2 amino acid sequence. Those positions where the EU sequence amino acids differ from the murine LL2 sequence are written between the nucleotide sequences. In FR4 the first three critical amino acid residues of murine LL2 are WGQ. The amino acid residues of EU at corresponding positions are EYN, and therefore, regardless of its best overall homology, choosing the whole EU framework for CDR-grafting was not a good choice. Since FR4 of heavy chain is encoded by the J gene, I then rationalized that FR4 did not necessarily have to come from the same human heavy chain. Both NEWM and KOL were a better fit for FR4 than EU because they have fewer residues that differ and because the first three critical residues are the same as those in the murine framework.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date

Shawn Leung, PhD.

From: (703) 726-6020
Marc Rossi

Origin ID: WGOA



20600 Gordon Park Square
Suite 150
Ashburn, VA 20147
UNITED STATES

SHIP TO: 7037266020

BILL SENDER

Dr. Shui-On Leung

10B, St. George Apartments
81 Waterloo Road

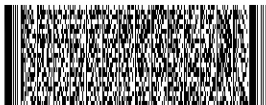
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REF: 09/988,013
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DESC-2:
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EEI: NO EEI 30.37(a)
COUNTRY MFG: US
CARRIAGE VALUE: 1.00 USD
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APPENDIX B

Rossi, Kimms & McDowell LLP

Intellectual Property Law

20609 Gordon Park Square
Suite 150
Ashburn, VA 20147

Phone: 703-726-6020
Fax: 703-726-6024
Mail@RKMLegalGroup.com

22 March 2011

Dr. Shui-On Leung
10B, St. George Apartments,
81 Waterloo Road,
Kowloon,
Hong Kong

Via Express Mail International

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/Barbara A. McDowell/

Barbara A. McDowell

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